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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,353	10/30/2003	Nawaz Ahmad	PPC-834-CIP-4	7581

27777 7590 06/23/2006

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EXAMINER	
ANTHONY, JOSEPH DAVID	
ART UNIT	**PAPER NUMBER**
1714	

DATE MAILED: 06/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/697,353	AHMAD ET AL.	
	Examiner	Art Unit	
	Joseph D. Anthony	1714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *1-16,18,19 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17,20-23 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. In response to applicant's response, filed 04/05/2006, to the written restriction requirement, mailed 03/17/2006, the examiner has decided to examine claim 17 along with elected claims 20-23 and 25. As such, the claims that will be examined are as followed: 17, 20-23 and 25.

Specification

2. The specification of the disclosure is objected to because drawing Figures 7-11 are not referenced under the "Brief Description Of The Drawings" Section of the specification. Correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 20-23 and 25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a **substantially anhydrous** lubricant composition comprising at least one polyol, wherein said composition increases in temperature by at least about 5°C upon exposure to moisture and which has a *"Maximum"?* Energy Release index of at least about 11 mJ/mg, does not reasonably provide enablement for a substantially **non-anhydrous** lubricant composition, see page 7, line 28 to page 8, line 33, and page 11, lines 10-14 of the specification. The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 17, 20-23 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's claims are deemed to be indefinite in regards to the claim limitation of: "wherein said composition increases in temperature by at least about 5°C upon exposure to moisture and which has a *Maximum* Energy Release index of at least about 11 mJ/mg [emphasis added]. Should not the word "Maximum" be replaced with the word –Minimum-- for the claims to make sense?

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

> applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 17 and 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative as being rejected under 35 U.S.C. 103(a) as being obvious over applicant's supplied English Language Translation of Akiyama et al. JP Application Publication Number 2-311408 or applicant's supplied English Language Translation of Osamu et al. JP Publication Number 2001-335429 or applicant's supplied English

Language Translation of Carreras et al. ES 2,074,030 or the English Language Abstract of WO 01/64176.

Akiyama et al., Osamu et al., Carreras et al. and WO all directly teach anhydrous or substantially anhydrous gel or gel-like therapeutic topical compositions for use on the human body such as the skin. The said therapeutic topical compositions comprise at least one polyol, such as propylene glycol, polyethylene glycol, glycerin or the like. The thickening agent can be hydroxyethyl cellulose or the like. Additional adjuvants well known in be used in therapeutic topical compositions, such as antimicrobial agents, anti-inflammatory agents, anti-septics, pH regulators, etc., can optionally be added to said compositions. All said therapeutic topical compositions are disclosed to generate heat of solution when they are brought in contact with moisture such as water. See at least the abstracts, examples and claims of each reference. Applicant's claims are deemed to be anticipated over the said disclosures and examples of each individual reference.

In the alternative, applicant's claims may be said to "differ" from Akiyama et al., Osamu et al., Carreras et al. and WO, in that none of these references directly states in writing applicant's claimed limitation of: "wherein said composition increases in temperature by at least about 5°C upon exposure to moisture and which has a *Maximum* Energy Release index of at least about 11 mJ/mg. Although, applicant's said limitation is not directly stated in writing, it is nevertheless deemed to be obvious to one having ordinary skill in the art to make compositions that meet applicant's claimed performance requirements, using the disclosure of each individual reference as

motivation because: 1) all said references teach therapeutic topical compositions that contain the same components as applicant's compositions in approximately the same concentration ranges, 2) All said references teach that their therapeutic topical compositions generate heat of solution when brought in contact with moisture, 3) all said references teach that the use of there therapeutic topical compositions is for application to human skin which by its very nature would require certain performance characteristic and limits to the amount of heat generated., and 4) applicant have set forth no showing of any criticality and/or superior and unobvious results for their claimed performance limitations.

10. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over applicant's supplied English Language Translation of Akiyama et al. JP Application Publication Number 2-311408 or applicant's supplied English Language Translation of Osamu et al. JP Publication Number 2001-335429 or applicant's supplied English Language Translation of Carreras et al. ES 2,074,030 or the English Language Abstract of WO 01/64176.

Akiyama et al., Osamu et al., Carreras et al. and WO, have been described above and differ from applicant's claimed method in that there is not a direct disclosure to the use of their therapeutic topical compositions in applicant's claimed method of treating dysmenorrheal. It would have been obvious to one having ordinary skill in the art to use the individual disclosure of each reference as motivation to actually use the disclosure therapeutic topical compositions in applicant's method of treating

dysmenorrheal since such as method is deemed to come within the broad disclosure of methods of use of the taught compositions.

11. Claims 17, 20-23 and 25 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ahmad et al. U.S. Patent Number 7,005,408.

Ahmad et al teach substantially anhydrous warming, non-toxic and nonirritating lubricating compositions containing polyhydric alcohols and an insulating agent. The invention also relates to methods of using such compositions for lubrication, administration of active ingredients and for preventing or treating dysmenorrhea. Applicant's claims are deemed to be anticipated over the examples of the patent, see abstract, examples and claims. Applicant's attention is drawn to the fact that applicant's specification in Example 9 directly teaches compositions 1-9 that are asserted by applicant to be composition of the invention, as such they must be compositions that meet the limitation of: "wherein said composition increases in temperature by at least about 5°C upon exposure to moisture and which has a *Maximum* Energy Release index of at least about 11 mJ/mg". Since the Ahmad et al patent directly teaches the same compositions 1-9, see columns 11-12, the Ahmad et al compositions must inherently meet applicant's claimed performance limitations.

NOTE: the examiner is well aware that applicant's pending application is a CIP application of S.N. 10/137,509 Now U.S. Patent Number 7,005,408. The new matter in all of applicant's claims is deemed to be the limitation of: "wherein said composition

increases in temperature by at least about 5°C upon exposure to moisture and which has a *Maximum* Energy Release index of at least about 11 mJ/mg". As such, the effective filing date of applicant's pending claims is 10/30/2003 which is the actual filing date of the present application. Since the filing date of U.S. Patent Number 7,005,408 is 05/01/2002, the patent qualifies as prior-art under 35 U.S.C. 102(e).

In the alternative, applicant's claims may be said to "differ" from Ahmad et al. in that the patent does not directly state in writing applicant's claimed limitation of: "wherein said composition increases in temperature by at least about 5°C upon exposure to moisture and which has a *Maximum* Energy Release index of at least about 11 mJ/mg. Although, applicant's said limitation is not directly stated in writing, it is nevertheless deemed to be obvious to one having ordinary skill in the art to make compositions that meet applicant's claimed performance requirements, using the disclosure of the patent as motivation because: 1) the patent teaches therapeutic topical compositions that contain the same components as applicant's compositions in approximately the same concentration ranges, 2) the patent teaches that the therapeutic topical compositions generate heat of solution when brought in contact with moisture, 3) the patent teaches that the use of there therapeutic topical compositions is for application to human skin and/or mucosal surfaces which by its very nature would require certain performance characteristic and limits to the amount of heat generated., and 4) applicant have set forth no showing of any criticality and/or superior and unobvious results for their claimed performance limitations.

Double Patenting

12. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

13. Claims 17, 20-23 and 25 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 15, 19-22 and 24 of copending Application No. 10/696,939. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 17, 20-23 and 25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 15, and 19-24 of U.S. Patent No. 7,005,408. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is massive overlap in the claimed subject matter.

16. Claims 17, 20-23 and 25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-18 of copending Application No. 10/697,383; as being unpatentable over claims 24-28 of copending Application No.10/389,871; as being unpatentable over claims 20-35 of copending Application No. 10/390,511; and as being unpatentable over claims 15 and 19-23 of copending Application No. 11/299,884. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pending claims in the present application are deemed to be a subset of the pending claims in said other pending applications.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Prior-Art Cited But Not Applied

17. Any prior-art reference which is cited on FORM PTO-892 but not applied, is cited only to show the general state of the prior-art at the time of applicant's invention.

Examiner Information

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Joseph D. Anthony whose telephone number is (571) 272-1117. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Vasu Jagannathan, can be reached on (571) 272-1119. The centralized FAX machine number is (571) 273-8300. All other papers received by FAX will be treated as Official communications and cannot be immediately handled by the Examiner.

Joseph D. Anthony
Primary Patent Examiner
Art Unit 1714

6/20/06